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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/542,821

10/21/2005

Luis Octavio Guisasola

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW

PO BOX 14329

RESEARCH TRIANGLE PARK, NC 27709

EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1628

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/542,821	<b>Applicant(s)</b> GUISASOLA ET AL.	
	<b>Examiner</b> Barbara P. Badio	<b>Art Unit</b> 1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-14 and 16-26 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-14 and 16-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

**First Office Action on the Merits of a RCE**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 9, 2009 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite because the metes and bounds of these claims can not be ascertained since they recite a process but are dependent on claim 18 which is drawn to a compound.

***Claim Rejections - 35 USC § 102***

**5. The rejection of claims 1, 5 and 8 under 35 USC 102(b) over Kim et al. (WO 96/30390) is withdrawn.**

**6. The rejection of claims 9 and 13 under 35 USC 102(b) over Kim et al. (WO 96/30390) is maintained and claims 18 and 23 are rejected under 35 USC 102(b) over Kim et al. (WO 96/30390).**

Applicant's argument is that the process of Kim is not a recrystallization process but a dissolution-evaporation process and, thus, does not allow one to purify the compound from impurities with different solubility since no separation of the resulting solid from impurities with different solubility is performed. Applicant's argument was considered but not persuasive for the following reason.

Crystallization is a known purification process and can be induced by cooling or evaporation of solvent (see for example, **US 2009/0186928**, section 0035; **US 6,026,656**, col. 1, lines 10-18; additional reference will be provided upon request). Therefore, the skilled artisan in the art would have the reasonable expectation that the solid containing isopropyl alcohol as solvent of recrystallization as taught by Kim is the isopropanol hemisolvate of VA-2914 as recited by the instant claims.

For this reason and those given in the previous Office Actions, the rejection of claims 9 and 13 under 35 USC 102(b) over Kim et al. (WO 96/30390) is maintained and claims 18 and 23 are rejected under 35 USC 102(b) over Kim et al. (WO 96/30390).

***Claim Rejections - 35 USC § 103***

**7. The rejection of claim 15 under 35 USC 103(a) over Kim et al. (WO 96/30390) in view of Cook et al. (WO 99/45022) is made moot by the cancellation of the instant claim.**

**8. The rejection of claims 2-4, 6, 7, 10, 12 and 14 under 35 USC 103(a) over Kim et al. (WO 96/30390) in view of Cook et al. (WO 99/45022) is maintained and claims 1, 5, 8, 13, 16, 17, 19-22 and 24-26 are rejected under 35 USC 103(a) over Kim et al. (WO 96/30390) in view of Cook et al. (WO 99/45022).**

Applicant's argument is that the instantly claimed process differs from that of Kim in the use of an intermediate recrystallization step from isopropanol, thus, providing VA-2914 isopropanol hemisolvate. Applicant also argues (a) the difference in the melting points of the prior art VA-2914 and VA-2914 obtained by the claimed process, (b) the recrystallization step from isopropanol allows one to improve the purity of the product, (c) Cook does not teach using recrystallization to purify the compounds and (d) neither Cook nor Kim discloses the specific combination of substituents required to arrive at the compound of claim 12. Applicant's argument was considered but not persuasive for the following reasons.

As noted above in #6, crystallization is a known purification process and can be induced by cooling as well as evaporation of solvent. Therefore, the dissolution and evaporation step taught by Kim is a purification step which results in the formation of solid, i.e., VA-2914 isopropanol hemisolvate.

The only difference between the claimed process and that taught by Kim is in the solvent utilized for the desolvation and crystallization of the obtained VA-2914 hemisolvate. However, Kim teaches the use of "ether" and discloses several ethers such as diethyl ether (see page 13, lines 3-6). Thus, the use of any ether, including those set forth by Kim on page 13, in the purification process as taught in Example 7 of Kim would have been *prima facie* obvious. Additionally, as noted in a previous Office Action, finding other solvents/solvent systems for crystallization of VA-2914 would require only routine experimentation.

Secondly, applicant argues the difference in melting points between VA-2914 obtained by Kim and that obtained by the claimed process. Applicant argues and the examiner agrees that the greater the amount of impurity present, the lower the melting point and the wider the melting range. Said would have been obvious to the skilled chemist in the art at the time of the present invention. Therefore, it would have been obvious to the skilled artisan to further purify said the VA-2914 obtained by Kim by recrystallization of the prior art taught Kim in Example 7. The skilled artisan would also have the reasonable expectation that further purification would result in improvement in the color of VA-2914.

Lastly, the examiner agrees the cited references do not specially teach the claimed carbinol acetate. Under 103, the issue is one of obviousness of the claimed compound. As noted in the previous Office Actions, Cook teaches a genus that encompasses the claimed carbinol acetate and, thus, as discussed therein, the claimed compound is rendered obvious.

In summary, Kim teaches the purification of 17 $\alpha$ -acetoxy-11 $\beta$ -(4-N,N-dimethylaminophenyl)-19-norpregna-4,9(10)-diene-3,20-dione (VA-2914) by dissolving the crude VA-2914 in isopropanol, evaporation of the solvent with the production of a solid which retains isopropanol, i.e., VA-2914 isopropanol hemisolvate followed by dissolution of said compound in ethyl acetate, evaporation of said solvent, dissolution of the obtained foam in ether and collection of the crystal formed. As noted in previous Office Actions and above, (a) finding the reaction condition(s), temperature for complete dissolution, crystallization by cooling as well as other solvents for crystallization of VA-2914 would require only routine experimentation and (b) the claimed carbinol acetate is made obvious by the genus taught by the Cook as discussed above and in the previous Office Actions.

For these reasons and those given in the previous Office Action, the rejection of claims 2-4, 6, 7, 10, 12 and 14 under 35 USC 103(a) over Kim et al. (WO 96/30390) in view of Cook et al. (WO 99/45022) is maintained and claims 1, 5, 8, 13, 16, 17, 19-22 and 24-26 are rejected under 35 USC 103(a) over Kim et al. (WO 96/30390) in view of Cook et al. (WO 99/45022).

### ***Telephone Inquiry***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio/  
Primary Examiner, Art Unit 1628